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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,802

10/21/2003

Yun He

021288-001910US

9439

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7590

07/03/2006

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EXAMINER

SAEED, KAMAL A

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/690,802	Applicant(s) HE ET AL.	
	Examiner Kamal A. Saeed	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9 and 10 is/are rejected.
- 7) ☒ Claim(s) 6-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/18/2003</u> | 6) <input type="checkbox"/> Other: _____  |

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***DETAILED ACTION***

Claims 1-17, are currently pending in the instant application. Claims 11-17 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

***Information Disclosure Statement***

Applicant's Information Disclosure Statement, filed on 18 February 2003 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

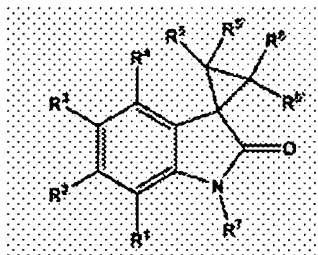
***Priority***

Applicants claim of the benefit of U.S. Provisional Application Nos. 60/420,482 and 60/420,481 both filed 21 October 2002 is acknowledged.

***Response to Restriction***

Applicant's election with traverse of Group I, claims 1-10 (all claims in part), drawn to

compounds of structural formula



as depicted in claim 1, and the specific

compound, , in response filed on 14 April 2006 is acknowledged.

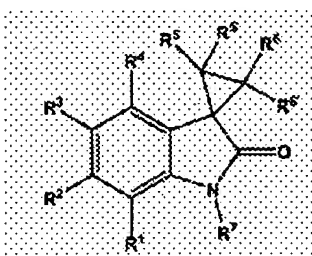
Applicants argue that the method of use should also be examined along with the elected compounds. In accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127

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(Fed. Cir. 1995), rejoinder of product claims and method of use claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process is deemed proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*The elected and examined subject matter is as follows:* The compounds of Formula I,



, of claim 1, wherein: **R<sup>1</sup> - R<sup>19</sup>** are as defined except that they don't represent a heterocyclic group.

The search was further extended to include the compounds of Formula I, wherein one of **R<sup>5</sup>** or **R<sup>5'</sup>** represents a 5-membered ring containing oxygen or sulfur as the only heteroatom.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as pyrimidinyl; piperidinyl; pyridyl, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S.

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classification system, i.e. class 544 subclass 224(+) (dizziness), class 546 subclass 184(+) (piperdines), 546 subclass 249(+) (pyridines) etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

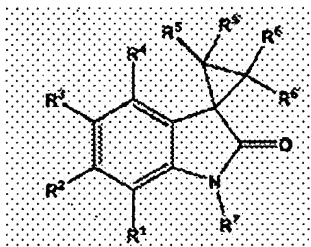
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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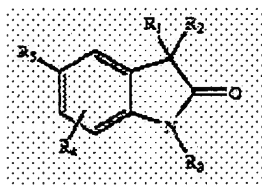
Claims 1-5, 9 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,391,907 B1 or U.S. Patent No. 6,608,068 B2 both to Fensome et al..

Instant elected claims disclose compounds and compositions of compound of the



formula depicted in claim 1, as defined above.

U.S. Patent No. 6,391,907 B1 teach in claim 1 and 10, compounds of formula



$R_1$  and  $R_2$  are joined to form a ring selected from the group consisting of:  
 $-\text{CH}_2(\text{CH}_2)_n\text{CH}_2-$ ;  $-\text{CH}_2\text{CH}_2\text{CMe}_2\text{CH}_2\text{CH}_2-$ ;  
 $-\text{O}(\text{CH}_2)_m\text{CH}_2-$ ;  $\text{O}(\text{CH}_2)_p\text{O}$ ;  
 $-\text{CH}_2\text{CH}_2\text{OCH}_2\text{CH}_2-$ ; and  $-\text{CH}_2\text{CH}_2\text{N}(\text{H or alkyl})\text{CH}_2\text{CH}_2-$ ;

$n$  is an integer from 0 to 5;

$m$  is an integer from 1 to 4;

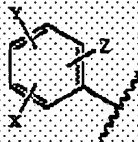
wherein:  $p$  is an integer from 1 to 4;

$R_3$  is selected from the group consisting of H, OH,  $\text{NH}_2$ ,  $\text{C}_1$  to  $\text{C}_6$  alkyl, substituted  $\text{C}_1$  to  $\text{C}_6$  alkyl,  $\text{C}_2$  to  $\text{C}_6$  alkenyl, alkynyl or substituted alkynyl, and  $\text{COR}^4$ ;

$R^4$  is selected from the group consisting of H,  $\text{C}_1$  to  $\text{C}_3$  alkyl, substituted  $\text{C}_1$  to  $\text{C}_3$  alkyl,  $\text{C}_1$  to  $\text{C}_3$  alkoxy, substituted  $\text{C}_1$  to  $\text{C}_3$  alkoxy,  $\text{C}_1$  to  $\text{C}_3$  aminoalkyl, and substituted  $\text{C}_1$  to  $\text{C}_3$  aminoalkyl;

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$R^2$  is a benzene ring with substituents X, Y and Z as shown below:

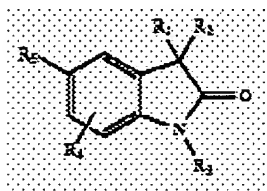


wherein:

X is selected from the group consisting of halogen, OH, CN,  $C_1$  to  $C_3$  alkyl, substituted  $C_1$  to  $C_3$  alkyl,  $C_1$  to  $C_3$  alkoxy, substituted  $C_1$  to  $C_3$  alkoxy,  $C_1$  to  $C_3$  thioalkyl, substituted  $C_1$  to  $C_3$  thioalkyl,  $S(O)$ alkyl,  $S(O)_2$ alkyl,  $C_1$  to  $C_3$  aminoalkyl, substituted  $C_1$  to  $C_3$  aminoalkyl,  $NO_2$ ,  $C_1$  to  $C_3$  perfluoroalkyl, 5 or 6 membered heterocyclic ring containing 1 to 3 heteroatoms,  $COR^B$ ,  $OCOR^B$ , and  $NR^C COR^B$ ;

$R^B$  is H,  $C_1$  to  $C_3$  alkyl, substituted  $C_1$  to  $C_3$  alkyl, aryl, substituted aryl,  $C_1$  to  $C_3$  alkoxy, substituted  $C_1$  to  $C_3$  alkoxy,  $C_1$  to  $C_3$  aminoalkyl, or substituted  $C_1$  to  $C_3$  aminoalkyl;

U.S. Patent No. 6,608,068 B2 teach in claim 1 and 10, compounds of formula



wherein:

$R_1$  and  $R_2$  are joined to form a ring selected from the group consisting of  $-CH_2(CH_2)_nCH_2-$ ,  $-CH_2CH_2C(CH_3)_2CH_2CH_2-$ ,  $-O(CH_2)_mCH_2-$ ,  $-CH_2CH_2OCH_2CH_2-$ ,  $-CH_2CH_2N(H)CH_2CH_2-$ , and  $-CH_2CH_2N(alkyl)CH_2CH_2-$ ;

$n$  is an integer from 0 to 5;

$m$  is an integer from 1 to 4;

$R_3$  is selected from the group consisting of H, OH,  $NH_2$ ,  $C_1$  to  $C_6$  alkyl, substituted  $C_1$  to  $C_6$  alkyl,  $C_1$  to  $C_3$  alkynyl, alkynyl, substituted alkynyl, and  $COR^A$ ;

$R^A$  is selected from the group consisting of H,  $C_1$  to  $C_3$  alkyl, substituted  $C_1$  to  $C_3$  alkyl,  $C_1$  to  $C_3$  alkoxy, substituted  $C_1$  to  $C_3$  alkoxy,  $C_1$  to  $C_3$  aminoalkyl, and substituted  $C_1$  to  $C_3$  aminoalkyl;

$R_4$  is selected from the group consisting of H, halogen, CN,  $NH_2$ ,  $C_1$  to  $C_6$  alkyl, substituted  $C_1$  to  $C_6$  alkyl,  $C_1$  to  $C_6$  alkoxy, substituted  $C_1$  to  $C_6$  alkoxy,  $C_1$  to  $C_6$  aminoalkyl, and substituted  $C_1$  to  $C_6$  aminoalkyl;

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- $R_5$  is selected from the group consisting of a), b) and c):
- a) a five membered heterocyclic ring having in its backbone 1, 2, or 3 heteroatoms selected from the group consisting of O, S, SO, SO<sub>2</sub> and NR<sup>6</sup> and containing one or two independent substituents selected from the group consisting of H, halogen, CN, NO<sub>2</sub>, C<sub>1</sub> to C<sub>3</sub> alkyl, C<sub>1</sub> to C<sub>3</sub> alkoxy, C<sub>1</sub> to C<sub>3</sub> aminoalkyl, COR<sup>D</sup>, and NR<sup>E</sup>COR<sup>D</sup>, with the proviso that when the five-membered heterocyclic ring having in its backbone one NR<sup>6</sup> heteroatom and said ring is attached at the 2-position on said ring, the CN substituent is attached at the 3 or 4-position of said ring;
- b) a six membered heterocyclic ring having in its backbone 1 or 2 heteroatoms selected from the group consisting of O, S, SO, SO<sub>2</sub> and NR<sup>6</sup> and containing one or two independent substituents selected from the group consisting of H, halogen, CN, NO<sub>2</sub>, C<sub>1</sub> to C<sub>3</sub> alkyl, C<sub>1</sub> to C<sub>3</sub> alkoxy, C<sub>1</sub> to C<sub>3</sub> aminoalkyl, COR<sup>D</sup>, and NR<sup>E</sup>COR<sup>D</sup>;
- $R^D$  is H, C<sub>1</sub> to C<sub>3</sub> alkyl, substituted C<sub>1</sub> to C<sub>3</sub> alkyl, aryl, substituted aryl, C<sub>1</sub> to C<sub>3</sub> alkoxy, substituted C<sub>1</sub> to C<sub>3</sub> alkoxy, C<sub>1</sub> to C<sub>3</sub> aminoalkyl, or substituted C<sub>1</sub> to C<sub>3</sub> aminoalkyl;
- $R^E$  is H, C<sub>1</sub> to C<sub>3</sub> alkyl, or substituted C<sub>1</sub> to C<sub>3</sub> alkyl;
- $R^6$  is H or C<sub>1</sub> to C<sub>3</sub> alkyl; and
- c) an indol-4-yl, indol-7-yl or benzo-2-thiophene moiety, the moiety being optionally substituted by from 1 to 3 substituents selected from the group

consisting of halogen, lower alkyl, CN, NO<sub>2</sub>, lower alkoxy, and CF<sub>3</sub>;

or a pharmaceutically acceptable salt thereof.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention is already covered by either one of the above-mentioned patents. This is specifically covered in U.S. '907 wherein  $R_1$  and  $R_2$  are joined to form a three membered ring i.e.  $-\text{CH}_2(\text{CH}_2)_n\text{CH}_2-$  and n is 0;  $R_3$  is H or alkyl group;  $R_5$  is a substituted benzene ring. This invention is also covered in U.S. '068 wherein  $R_1$  and  $R_2$  are joined to form a three membered ring i.e.  $-\text{CH}_2(\text{CH}_2)_n\text{CH}_2-$  and n is 0;  $R_3$  is H or alkyl group;  $R_5$  is a heterocyclic ring. ring Patent No. 6,716,834 which are more specific embodiments that anticipate the compounds and compositions as instantly claimed and one skilled in the art would



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have been motivated to make specific compounds similar to the one described and exemplified in either of the patents with the expectation of making compounds for pharmaceutical application.

### ***Objections***

Claims 6-8, are objected to for depending on a rejected base claim.

Claims 1-10 are objected to for containing non-elected subject matter.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal Saeed whose telephone number is (703) 308-4592. The examiner can normally be reached on Monday-Friday from 8:00 AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308 4537. The unofficial fax phone for this group are (703) 308-4556 or 305-3592.

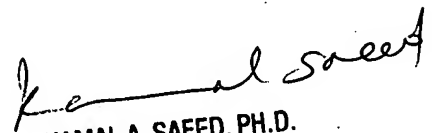
When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive

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data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

  
KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER